Transcript of Horst Koller, Volume 2

Date: May 16, 2022
Case: Regeneron -v- Novartis (PTAB)

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231

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

REGENERON PHARMACEUTICALS, INC.

Petitioner,

V.

NOVARTIS PHARMA AG,

NOVARTIS TECHNOLOGY, LLC,

NOVARTIS PHARMACEUTICALS CORPORATION,

Patent Owners

Patent Number:

9,220,631

CONTINUED DEPOSITION OF HORST KOLLER

Monday, May 16, 2022

Reported by:

STEPHANIE A. BATTAGLIA, CSR, RMR, CRR

Job No.: 448280

232

May 16, 2022

6:03 a.m., Central Time

Continued Deposition of HORST KOLLER, held virtually, before Stephanie A. Battaglia, a Registered Merit Reporter, Certified Realtime Reporter, and Notary Public of the State of Illinois.

233

PRESENT: (All appeared via Zoom Conference)

WEIL, GOTSHAL & MANGES
BY: MR. CHRISTOPHER PEPE
2001 M Street NW
Washington, D.C. 20005
(202) 682-7153

- and -

WEIL, GOTSHAL& MANGES
BY: MR. TOM YU
767 Fifth Avenue
New York, New York 10153-0119
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appeared on behalf of the Petitioner;

ALLEN & OVERY
BY: MR. WILLIAM JAMES
1101 New York Avenue, NW
Washington, D.C. 20005
(202) 683-3895

- and -

ALLEN & OVERY
BY: MR. MATTHEW MINER
One Beacon Street
Boston, Massachusetts 02108
(857) 353-4509

appeared on behalf of the Patent Owners.

ALSO PRESENT:

Ms. Petra Scamborova
Mr. Andrew Gesior
Regeneron

Ms. Rachel Carrick, Technician
Ms. Stephanie A. Battaglia, CSR, RMR, CRR
Planet Depos

234

I N D E X

235

(Cont'd.):

236

MS. REPORTER: Here begins the videoconference deposition of Koller Horst in the matter of Regeneron versus Novartis.

Today's date is May 16, 2022, and the time is 6:03 a.m., Central Time.

My name is Stephanie Battaglia of Planet Depos.

Beginning with the noticing party, will counsel please introduce themselves, state whom they represent, and stipulate to the swearing in of the witness remotely.

Mr. James?

MR. JAMES: My name is William James from Allen & Overy on behalf of the Patentee Novartis, and I can confirm that I agree to that.

MR. PEPE: Chris Pepe representing Petitioner Regeneron. With me is Tom Yu, also with Weil, Gotshal. And we have on the line Petra Scamborova and Andrew Gesior with Regeneron, and we confirm as well.

MR. JAMES: If I could -- sorry to interrupt, I also have Matthew Miner from Allen & Overy on the line today.

237

KOLLER HORST,

called as a witness herein, having been first duly sworn was examined and testified virtually as follows:

EXAMINATION

BY MR. JAMES:

Q Hello, Mr. Koller.

A Good morning, Mr. James.

Q Thank you for taking the time to talk to us.

So just, let's see, we took your deposition last December, do you recall that?

A Right, I recall that.

Q And have you given any other testimony since that time?

A No, I haven't.

Q Have you picked up any additional consulting work on prefilled syringes since that time?

A Yes, I have.

Q For Regeneron?

238

A No.

Q Does the prefilled syringe -- let me strike that.

Is it a prefilled syringe for intravitreal administration?

A I am not sure yet because I am helping this company to build up an overall syringe business, so it is not specific product-related, it is more from the technical point of view how to make a syringe pump basically.

Q I see.

Can you tell me what you did to prepare for your deposition today?

A I was reading of course my reply declaration with related exhibits.

Q Anything else?

A I had a couple of talks with my counsel.

Q Other than counsel did you speak with anybody else about your deposition?

A No.

Q When did you speak with counsel?

A Last week.

239

Q On how many occasions?
A It was three occasions.
Q For approximately how long in total?
A Between eight and ten hours.
Q Did you review any documents in preparation for your deposition other than the documents that are cited in your reply declaration?
MR. PEPE: Objection to the extent it calls for privilege.
Horst, you can answer yes or no if you remember.
THE WITNESS: Yes, I remember.
BY MR. JAMES:
Q You recall reviewing documents outside of the documents that are cited in your declaration?
A Yes.
Q Were those scientific articles?
A One I was mentioning was an ISO standard.
Q Which ISO standard is that?
A It is ISO standard 11135.
Q And why did you review that ISO standard

240

standard?
MR. PEPE: Objection, calls for privilege.
Horst, you can answer to the extent you can do so without divulging any of the communications we had during our meetings.
THE WITNESS: This standard talks about EtO sterilization and process.
BY MR. JAMES:
Q Beyond ethylene oxide sterilization and processes do you recall any other -- any of the other contents of ISO 11135?
A No.
Q Was that ISO standard cited by an expert in this matter?
A I would need to go back to my original declaration if -- it was not cited, I am not sure if I gave that as an answer to you that you might follow certain ISO standards which are related to ASTM standards, but I am not too familiar from European standards with ASTM standards so my focus was usually more on the ISO standard, this is where the relation comes from.

241

Q And can you just tell me generally what 11135 is about?
A It shows you this is a guideline on process development or cycle development, possible related validation of EtO cycling, and it gives you a couple of options how to do that and how to approach that.
Q Does it talk about the validation of a sterility assurance level?
A It is mentioning sterility assurance level in general terms.
Q Does it provide for a method of achieving any particular sterility assurance level?
A It is giving you a proposal how to achieve the -- for the product specific required sterility assurance level.
Q So the process would be able to achieve a sterility assurance level of, for example, 10 to the minus 3, is that right?
A It would give you guideline to do that if you pre-specify SAL 10 to the minus 3, yes.
Q And if you elected to you could select a

242

different SAL such as 10 to the minus 6, would that be right?
A Yes. Then you need to follow a certain principle, which is pretty much the same. The principals there are described in general terms, and then depending on the required SAL they just you know what you would need to do.
Q Does it indicate in the ISO 11135 that the ethylene oxide can damage some drug products?
MR. PEPE: Object to form.
THE WITNESS: I would need to pull it up. I mean, it is divided into whether it addresses two parts, one is the sterility part and one is the functional terms of the device to sterilize.
BY MR. JAMES:
Q The actual device that's used?
A They talk about device in general terms, they don't give specifics, give specific -- it gives a guidance how to achieve -- what kind of approaches you have to achieve certain SAL levels, and one is focusing on the microbiology, which is the sterility, and then it gives the indication to

243

say, okay, that functional performance needs to be checked as part of the overall approach.

Q Mr. Koller, do you have a copy of Boulange?

A Yes, if you can send me the exhibit number, I have a bunch of files here from the list with tab numbers and exhibit numbers.

Q Okay, one moment.

A I think this is Boulange, it is 1008.

Q That's right, yes. So if you can open Exhibit 1008, please.

(Document identified as Exhibit 1008 for identification.)

BY MR. JAMES:

Q Do you have a copy of your declaration -- sorry, your reply declaration there in front of you?

A It's listed as Exhibit 1003.

(Document identified as Exhibit 1003 for identification.)

BY MR. JAMES:

Q I believe Exhibit 1003 was original

244

declaration in the IPR.

Your reply declaration is Exhibit 1105.

THE TECHNICIAN: Sir, I have that as Tab 67.

MR. JAMES: I apologize.

THE WITNESS: I just found it.

MR. JAMES: I will try to call the tabs out. I appreciate the help.

(Document identified as Exhibit 1105 for identification.)

THE WITNESS: I have now my reply declaration and Boulange patent in front of me.

BY MR. JAMES:

Q Okay, great.

It is a patent application, right?

A It is a WO number, yes.

Q It's a patent application, correct?

A Patent application.

Q And then this declaration, 1105, your rely declaration, it was signed by you on the 12th of April of this year, is that right?

A That's right.

245

Q And how many hours did you spend putting this together, Mr. Koller?

A In total 50, 50, 60 hours.

Q And would you say you spent more time on it or the lawyers?

A I spent more --

MR. PEPE: Object to form, calls for speculation.

THE WITNESS: I mean, I don't know how much time the lawyers spent, but it is based on my original declaration, which is baseline for my reply declaration, so, as I said, I spent approximately 50 to 60 hours.

BY MR. JAMES:

Q And how did the process work, did you actually draft this declaration on the computer or did you -- or did the lawyers provide you with the drafts?

MR. PEPE: Object to form.

THE WITNESS: The lawyers provided me with a general draft and then I was going through and made my expert comments and then they had me to

246

put it into the right language. As you might hear English is not native language, so they helped me also in sort of some of the language issues I had here.

BY MR. JAMES:

Q So they provided you with a draft and then you provided comments and they helped with the language, is that right?

A That's right.

MR. PEPE: Object to form.

BY MR. JAMES:

Q And if you could look at Paragraph 28 -- I am going to apologize, I am going to be jumping around a little bit today, sorry for that.

A 28.

Q 28, yes.

28 is under a heading where you say that the Parylene-C wouldn't need to come into contact with the VEGF-Antagonist, right?

A Right.

Q And in the middle of the paragraph you say that Boulange describes that the Parylene-C

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